

memo

to Dr. Paul Goldenheim
from Ben Oshlack *for review*
dept Pharmaceutical Development
subject Acrocontin System
date July 24, 1992

The patented contin system teaches that the release of a drug substance can be retarded and controlled by incorporating the drug into a matrix which contains a hydrophilic cellulose polymer and a higher aliphatic alcohol. The combination of these two different polymer types shows a potentiation with respect to the ability to retard the release of the drug substance. When oxycodone HCl was incorporated into the contin matrix, the drug was in fact retarded, however, we were not able to achieve a dissolution that was slow enough to meet the profiles of the established MS CONTIN, even when the quantity of the retardants were increased.

It was observed that an equal w/w substitution of the cellulose polymer with an acrylic resin in combination with the same quantity of higher aliphatic alcohol, the oxycodone HCl release was further retarded, and the dissolution finally matched that of the MS CONTIN 30 mg.

A patent covering the potentiation of the retardation of the combination of an acrylic resin together with a higher aliphatic alcohol was then filed worldwide. Approval has already been received in the US (Patent number 4,861,598, August 29, 1989). This is called the Acrocontin delivery system.

Therefore the successful development of an oxycodone controlled release tablet for twice-a-day administration required the development of a new and novel technology.

cc: Mark Chasin

Trial Exhibit

Purdue et al. v. Endo et al.
Nos. 00 Civ. 8029 (SHS);
01 Civ. 2109 (SHS); 01 Civ. 8177 (SHS)

DX 3272

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Deposition Exhibit

Purdue et al. v. Endo et al.
Nos. 00 Civ. 8029 (SHS);
01 Civ. 2109 (SHS); 01 Civ. 8177 (SHS)

DX 105